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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/715,665 | 11/17/2003 | Mark Selby | PP01635.007 | 5235 |

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| EXAMINER | |
|---|---|
| LUCAS, ZACHARIAH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/715,665 | SELBY ET AL. | |
| | Examiner | Art Unit | |
| | Zachariah Lucas | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 46-61, drawn to Virus-like particles comprising a Hepatitis B surface antigen (HBsAg) and at least one chimeric HBsAg fused to an HCV immunogenic polypeptide, classified in class 424, subclass 192.1.

II. Claims 22-25, drawn to a fusion protein comprising an HBsAg S domain and an HCV E1 polypeptide, classified in class 424, subclass 192.1.

III. Claims 26-29, drawn to a fusion protein comprising an HBsAg S domain and an HCV E2 polypeptide, classified in class 424, subclass 192.1.

IV. Claims 30-69, 77, and 78, drawn to a nucleic acid encoding a fusion protein comprising an HBsAg S domain and an HCV E1 polypeptide, classified in class 536, subclass 23.4.

V. Claims 70 and 71, drawn to methods for producing VLP comprising the expression of HBV HBsAg and chimeric HBsAg in a cell culture, classified in class 435, subclass 69.1.

VI. Claims 72-75, drawn to methods of producing cell lines that produce HBsAg VLPs, classified in class 435, subclass 455.

**For Groups I and IV above**, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VI, and, if one of Groups I or IV is elected, then election is also required to one of subgroups (A)- (C). Subgroups (A)-(C) represent distinct inventions wherein the claimed VLP comprises a HBsAg, or the claimed nucleic acids (or cells comprising them) encodes and:

(A) a chimeric HBsAg fused to an HCV E1 protein;
(B) a chimeric HBsAg fused to an HCV E2 protein; or
(C) a chimeric, HBsAg fused to an HCV E1 protein and a second chimeric HBsAg fused to an HCV E2 protein.

**For Groups V and VI above**, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VI, and, if one of Groups V or VI is elected, then election is also required to one of subgroups (A)- (B) as described above.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups A and B are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, the inventions of either of subgroups A or B have the same, but separate, utility as the inventions of the other subgroups. The inventions are therefore distinct.

3. The inventions of subgroups (C) and either of subgroups (A) or (B) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination may rely on the limitations of either of the subcombinations, or on the totality of the combination's limitations. The subcombinations each have separate utility such as for use in the immunogenic compositions. The inventions are therefore distinct.

4. The inventions of Group I- III, and of Groups IV-VI are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to compositions and methods relating to different types of compounds. In particular, the two sets of Groups are drawn to polypeptides (or compositions comprising such) and to polynucleotides that encode them (and compositions or methods of use thereof).

Inventions I-III are patentably distinct products.

The polypeptides and polynucleotides are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, while the polypeptides can made by methods using the polynucleotides, it can also be recovered by other means, such a by protein synthesis or fusion. Furthermore, the information provided by the polynucleotide of group I can be used to make materially different polypeptides that those claimed. For example, a nucleic acid which hybridizes to a sequence 1, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with the protein sequence. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of these groups together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not

coextensive. These types of molecules have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. In addition, both sets of inventions include embodiments with a percent identity to the sequences identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature.

Additionally, in this case the claims are drawn to immunogenic compositions including either of the two types of molecules. Each of these compositions requires an independent search, as a search for immunogenic compositions comprising a protein would not necessarily provide any indication as to patentability of polynucleotide compositions.

As such, it would be burdensome to search the inventions comprising these types of molecules together.

5. The inventions of Groups II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, the inventions of Group II have the same utility as the inventions of Group III.

6. The inventions of Group I are related as combination and subcombinations with the inventions of Group II and III. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the inventions of these Groups are distinct for substantially the same reasons as indicated with respect to subgroups (A)-(C) above. In this case,

the fusion proteins of Groups II and III may be used in the claimed VLPs, or may be used individually as anti-HCV immunogens. The inventions are therefore distinct.

7. The inventions of Group IV are related as product and process of use with the methods of Groups V and VI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed products may be used in either of the claimed methods, or in methods of inducing an immune response in an animal. The inventions are therefore distinct.

***Conclusion***

8. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

9. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 11/29/04
SUPERVISORY PATENT EXAMINER
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